JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

STEPHANIE TEOLI

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
THOMAS R. ANAPOL, ESQUIRE, ANAPOL SCHWARTZ, 1710 Spruce Street, Phila., PA 19103 (215) 735-1130

DEFENDANTS

Howmedica Osteonics Corporation, a New Jersey corporation, d/b/a STRYKER ORTHOPAEDICS

County of Residence of First Listed Defendant BERGEN COUNTY, NJ
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff) and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. § 1332(a) - diversity

Brief description of cause:
Hip replacement device failure

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
03/18/2013

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

STEPHANIE TEOLI,	)	
	)	**CIVIL ACTION**
PLAINTIFF,	)	
	)	
vs.	)	
	)	
HOWMEDICA OSTEONICS CORPORATION, a New Jersey corporation, d/b/a STRYKER ORTHOPAEDICS,	)	**NO.:**
	)	
	)	**JURY TRIAL DEMANDED**
DEFENDANT.	)	

COMPLAINT

Plaintiff STEPHANIE TEOLI ("Plaintiff"), by and through the undersigned counsel, brings this Complaint against Defendant HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS Defendant" or "Howmedica" or "Stryker") for personal injuries and damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "The Rejuvenate® System," which includes ABGII Modular Stems, ABGII Modular Necks, Rejuvenate Modular Neck and Stem components (hereinafter "Rejuvenate" or "Defective Device"), and Plaintiff further alleges as follows:

PARTIES

1. Plaintiff STEPHANIE TEOLI is a resident of the Oreland, Montgomery County, Pennsylvania.

2. Defendant Howmedica is a corporation organized and existing under the laws of New Jersey having its principal place of business located at 325 Corporate Drive, Mahwah, New

Jersey 07430 and conducts business throughout the United States including in the State of New Jersey and Commonwealth of Pennsylvania. Defendant Howmedica also is doing business as "Stryker Orthopaedics."

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction under the diversity of citizenship statute, 28 U.S.C. § 1332. Plaintiff and Defendant are citizens of different states, and complete diversity of citizenship exists as between Plaintiff and Defendant. Moreover, Plaintiff seeks damages in excess of $75,000, exclusive of interest and costs.

4. Venue is proper in this Court because at all times relevant to this Complaint, Defendant has engaged in continual business in this District, and Defendant receives substantial compensation and profits from sales of "The Rejuvenate System" in this District.

GENERAL FACTUAL ALLEGATIONS

History of the Stryker Rejuvenate System

5. On June 3, 2008, Defendant received FDA clearance to sell its Rejuvenate System in the United States.

6. The Rejuvenate System is a dual modular hip replacement prosthesis. It is indicated for patients requiring primary total hip arthroplasty or replacement due to painful joint disease of the hip resulting from non-inflammatory degenerative arthritis.

7. Unlike most prosthetic hip implants, the Rejuvenate System is an artificial hip replacement device consisting of two basic components: a chrome cobalt neck that is inserted into a titanium stem.

8. The Rejuvenate System is comprised of separate femoral stem and neck components and offers a variety of sizing options intraoperatively. The benefit according to

Stryker was that by allowing the surgeon to independently manage leg length, neck version, and femoral offset, the system provides surgeons the ability to better personalize the biomechanics of each patient's hip replacement implant.

9. The Rejuvenate System can be used interchangeably with any number of Stryker bearing surface components which comprise the ball and an acetabular cup or socket. The bearing surface system or components are unrelated to the Rejuvenate System's method of failure.

10. The titanium stem is manufactured utilizing a proprietary titanium alloy consisting of titanium, molybdenum, zirconium, and iron. This alloy was designed and patented by Defendant and is unlike any titanium alloy employed in the manufacture of other prosthetic hip implants.

11. The Rejuvenate System combines the material characteristics of TMZF (Ti-12Mo-6Zr-2Fe) with a plasma sprayed coating of commercially-pure Ti and PureFix HA for the stem and CoCr for the neck. Defendant claims that laboratory testing demonstrates the compatibility of these materials without concern for fretting and corrosion.

12. Defendant claims in its promotional materials for the Rejuvenate System that its titanium alloy is both stronger and less rigid than other titanium alloys. Defendant also claims that the particular titanium alloy has been tested and proven by Defendant to resist the effects of corrosion and fretting.

13. Despite Defendant's claims, this combination of materials has been reported to cause fretting, galvanization, and corrosion. Since the 1980s, medical and scientific literature has reported corrosion to be a problem when Ti and CoCr have been used at modular junctions in

medical implants. In its marketing and sale of the device, Defendant represented and warranted that its proprietary materials alleviate this problem.

14. In February 2009, Stryker released its Rejuvenate Modular Primary Hip System, the latest evolution in the Defendant's OmniFit and Secure-Fit Hip systems.

15. The Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which was approved for market by the FDA on Sept 13, 2007.

16. According to Defendant's materials, the Rejuvenate Modular Primary Hip System was developed to optimize anatomic restoration by providing options that offer enhanced stability, proven modularity, and intra-operative flexibility. With a wide range of femoral stem and neck combinations and an extensive range of length, version, and offset, the Rejuvenate Modular Primary Hip System was marketed to enable surgeons to better personalize the implant to each patient's unique anatomy.

17. Defendant holds two patents for modular implant devices. Currently, Defendant has a pending application to patent a modular hip prosthesis similar to the Rejuvenate System.

Urgent Safety Notices and Recalls

18. In April of 2012, Defendant issued an Urgent Field Safety Notice to surgeons and hospitals in the United States regarding the Rejuvenate System.

19. In this notice, Defendant acknowledged that it had received reports of device failure due to heavy metal contamination. The Urgent Field Safety Notice specifically referred to failures at the taper neck junction between the neck and stem due to corrosion and fretting.

20. This corrosion and fretting was exactly the same failure mechanism that Defendant had warranted would not occur because of the Rejuvenate System's design and composition. It was also exactly the same failure mechanism that the medical and scientific

community had been studying and documenting in modular implant device design since the 1980s.

21. The Urgent Field Safety Notice went on to describe symptoms and findings identical to those experienced by Plaintiff herein.

22. Among those symptoms and findings specifically mentioned in the Urgent Field Safety Notice were tissue necrosis, metallosis, adverse soft tissue reaction, and pseudotumor formation.

23. Almost immediately following the Urgent Field Safety Notice, Defendant issued a voluntary recall of the Stryker Rejuvenate and ABGII in Canada. In the Canadian recall notice, Defendant stated that it was amending the Instructions for Use for the Rejuvenate System to include warnings that Defendant was on notice of the issues described in the Urgent Field Safety Notice above.

24. Finally, in the first week of July of 2012, Defendant issued a voluntary recall of all Stryker Rejuvenate and ABG II stems in the United States. As part of the July of 2012 recall notice, Defendant once again cited reports of device failure due to heavy metal fretting and corrosion.

Federal Regulations

25. Federal regulation states: "Recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." *See* 21 CFR §7.3(g).

26. Federal regulation states: "Recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to

indicate the relative degree of health hazard presented by the product being recalled." *See* 21 CFR §7.3 (m).

27. Federal regulation states: "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." *See* 21 CFR §7.3 (m).

28. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

29. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

30. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. *See* 21 U.S.C. §352.

31. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or

serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. §360(i).

32. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR §803.50.

33. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR §803.52.

34. Pursuant to federal regulations, manufacturers must report any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. *See* 21 CFR §803.53.

35. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals and must also maintain records of device corrections

and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR §806.

36. Pursuant to federal regulations, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Further, Manufacturers are required to use statistical techniques, where necessary, to evaluate product performance. *See* 21 CFR §820.

37. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of its devices. Federal regulations require that: "A PMA supplement must be submitted when

unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." *See* 21 CFR §814.

38. Specifically, it is believed that with respect to the Rejuvenate System, Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

SPECIFIC ALLEGATIONS REGARDING PLAINTIFF

39. At all times material hereto, Defendant developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold "The Rejuvenate® System," either directly or indirectly, to members of the general public within the Commonwealth of Pennsylvania and the State of New Jersey, including Plaintiff.

40. Defendant's Rejuvenate System was placed into the stream of interstate commerce and was implanted in Plaintiff STEPHANIE TEOLI at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, on January 24, 2011.

41. As a direct and proximate result of Defendant placing the Rejuvenate System into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; past, present and future medical, hospital, rehabilitative and pharmaceutical expenses; lost wages; and other related damages.

42. At all times material hereto, the Rejuvenate stem and neck implanted in Plaintiff were designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendant.

43. After the implantation of the Rejuvenate System, Plaintiff STEPHANIE TEOLI began experiencing significant pain and discomfort in the area of the Rejuvenate System.

44. Diagnostic workup revealed the absence of device loosening, infection, malposition, or any other explanation for Plaintiff's symptoms.

45. Further diagnostic workup revealed blood test results indicating the presence of heavy metal ion contamination and MRI results revealed adverse local tissue reaction and dehiscence at the posterior capsule.

46. Based upon these findings and in light of worsening symptoms, Plaintiff underwent revision surgery on August 8, 2012. During that surgery, it was discovered that, in fact, there was significant corrosion on Defendant's Rejuvenate System.

CAUSES OF ACTION

COUNT I – BREACH OF EXPRESS WARRANTY

47. Plaintiff incorporates by reference all allegations in the preceding paragraphs as if fully set forth herein and further alleges as follows.

48. Through their public statements, their descriptions of the Rejuvenate System, and Defendant's promises relating to the Rejuvenate System, Defendant expressly warranted, among other things, that the Rejuvenate System was efficacious and safe for its intended use; was designed and constructed of materials that would prevent fretting and corrosion; would last longer that competing hip implant devices; and was more suitable for younger adults than other devices given its purported longevity.

49. These warranties came in the form of (i) publicly-made written and verbal assurances of safety; (ii) press releases and dissemination via the media of uniform promotional information that was intended to create demand for the Rejuvenate System (but which contained material misrepresentations and utterly failed to warn of the risks of the Rejuvenate System); (iii) verbal assurances made by Defendant's consumer relations personnel to the public about the safety of the Rejuvenate System that also downplayed the risks associated with the Rejuvenate System; and (iv) false and misleading written information supplied by Defendant.

50. The most prominent representation made by Defendant was on its website where it expressly warranted that the design, testing, and materials utilized in the Rejuvenate System would prevent fretting and corrosion.

51. Plaintiff herein further alleges that all of the aforementioned written materials are known to Defendant and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Defendant and be made of record once Plaintiff is afforded the opportunity to conduct discovery.

52. When Defendant made these express warranties, Defendant knew the purpose for which Rejuvenate System was to be used and warranted it to be in all respects safe and proper for such purpose.

53. Defendant drafted the documents and/or made the statements upon which these warranty claims are based and, in so doing, defined the terms of those warranties.

54. Defendant's representations and promises regarding the Defective System had the natural tendency to induce those in need of prosthetic hip implants, including Plaintiff, to purchase the Defective Device in reliance thereon.

55. The Rejuvenate System does not conform to Defendant's representations in that the devices are not safe and produce serious side effects.

56. As such, the Rejuvenate System did not conform to Defendant's promises, descriptions, or affirmations of fact and was not adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used.

57. Defendant therefore breached its express warranties to Plaintiff herein in violation of applicable state statutes and the Uniform Commercial Code, by manufacturing, marketing, and selling the Rejuvenate System to Plaintiff herein and causing damages as will be established at trial.

COUNT II – STRICT PRODUCTS LIABILITY FAILURE TO WARN

58. Plaintiff incorporates by reference all allegations in the preceding paragraphs as if fully set forth herein and further alleges as follows.

59. The Rejuvenate System implanted into Plaintiff STEPHANIE TEOLI contained no warnings or, in the alternative, inadequate warnings as to the risk that the product could cause fretting, corrosion, and significant heavy metal toxicity. Similar, although still inadequate, warnings were added in 2012 by Defendant. Defendant acted unreasonably in failing to provide such warning or instruction prior to 2012.

60. The warnings that accompanied the Rejuvenate System failed to provide that level of information that an ordinary consumer would expect when using the implant in a manner reasonably foreseeable to the Defendant. Moreover, the Rejuvenate System left the Defendant's control, the Rejuvenate System, without an adequate warning or instruction, and created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm. Alternatively, after the

Rejuvenate System left the Defendant's control, it became aware of, or in the exercise of ordinary care should have known, posed a substantial risk of harm and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

61. Had Plaintiff STEPHANIE TEOLI received a proper or adequate warning as to the risks associated with using the implant, Plaintiff STEPHANIE TEOLI would not have used the product.

62. Had Plaintiff's surgeon received a proper or adequate warning as to the risks associated with using the Rejuvenate System, Plaintiff's surgeon would not have recommended the device; would have used an alternate device; or, at a minimum, would have provided Plaintiff STEPHANIE TEOLI with adequate warning and obtained informed consent.

63. Defendant's failure to warn of the Rejuvenate System's risks caused serious damage to Plaintiff STEPHANIE TEOLI, including bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

64. Defendant's intentional disregard for the safety of patients who were implanted with Rejuvenate systems, including Plaintiff, justifies an award of punitive damages.

COUNT III – STRICT PRODUCTS LIABILITY DESIGN DEFECT

65. Plaintiff incorporates by reference all allegations in the preceding paragraphs as if fully set forth herein and further alleges as follows.

66. This is an action for strict liability based upon design defect against Defendant.

67. Defendant's Rejuvenate System is designed in such a way that, when used as intended, the Rejuvenate System causes serious, permanent, and devastating damage to patients in whom the devices are implanted. The damage and mechanism of injury have been previously described herein, and Defendant acted unreasonably in its design of the Rejuvenate System such that at the time the Rejuvenate system left Defendant's control in that Defendant unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevent or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.

68. Defendant's Rejuvenate System does not perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant.

69. The risks of using Defendant's Rejuvenate System outweigh the benefits of using the devices.

70. There were numerous safer alternative designs to the defective Rejuvenate stem which in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's personal injury without substantially impairing the product's utility and was economically and technologically feasible at the time the product left the control of the manufacturer or seller by the application of existing or reasonably achievable scientific knowledge.

71. The Rejuvenate System installed in Plaintiff's hip was defectively designed.

72. The design defect in Defendant's Rejuvenate System caused serious damage to Plaintiff STEPHANIE TEOLI, including bodily injury; pain and suffering; disability; physical impairment; disfigurement; mental anguish; inconvenience; aggravation of a pre-existing condition; loss of the capacity for the enjoyment of life; the costs of medical care and expenses; loss of earnings; and loss of the ability to earn money, all of which damages and losses will continue in the future.

73. Defendant's intentional disregard for the safety of patients who were implanted with Rejuvenate systems, including Plaintiff, justifies an award of punitive damages.

COUNT IV - NEGLIGENCE

74. Plaintiff incorporates by reference all allegations in the preceding paragraphs as if fully set forth herein and further alleges as follows.

75. Defendant had a duty to exercise reasonable care in advertising, analyzing, assembling, compounding, designing, developing, distributing, formulating, inspecting, labeling, manufacturing, marketing, monitoring the use of, packaging, producing, promoting, processing, researching, testing, issuing warnings with respect to, and selling REJUVENATE®, and to adequately test and warn of the risks and dangers of REJUVENATE®, both before and after sale, and to recall the products upon discovering that the warnings and information issued in connection with REJUVENATE® were inadequate, and that prescribing physicians and consumers did not fully understand the risks associated with REJUVENATE®.

76. Defendant, through its agents, servants, and/or employees acting within the course and scope of their employment, breached its duty to exercise reasonable care in one or more of the following ways:

a. failing to conduct sufficient testing which, if properly performed, would have shown that REJUVENATE® could lead to fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors;

b. failing to disclose adverse test results and other information regarding the risk that REJUVENATE® use could lead to fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors;

c. failing to review all adverse drug event reports;

d. failing to continually test, monitor, and analyze data regarding the safety, efficacy, and use of REJUVENATE®;

e. failing to adequately warn the medical community and consumers, including Plaintiff and her surgeon, of the risks of fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors associated with REJUVENATE®;

f. negligently designing the REJUVENATE® to include metals and/or materials it knew or should have known, that when used as designed, would result in fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, pseudotumors and/or other injury and need for further surgery and/or revision.

g. misrepresenting that REJUVENATE® was safe for use when it knew or should have known that it was associated with fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors;

h. failing to conduct post-marketing safety surveillance and report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of adverse effects

associated with REJUVENATE®, to the medical community and consumers, including Plaintiff and her surgeon;

i. failing to provide post-marketing warnings after Defendant knew or should have known of the significant risks of fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors associated with REJUVENATE®; and

j. promoting and marketing REJUVENATE® as safe and effective for use when Defendant knew or should have known that REJUVENATE® was associated with a risk of fretting, corrosion, tissue necrosis, metallosis, adverse soft tissue reaction, and/or pseudotumors.

77. As a consequence of one or more of the foregoing acts or omissions, Defendant failed to act as a reasonably prudent medical device manufacturer.

78. As a direct and proximate result of Defendant's negligence, Plaintiff suffered injuries and damages as described above.

79. Defendant's intentional disregard for the safety of patients who were implanted with Rejuvenate systems, including Plaintiff, justifies an award of punitive damages.

COUNT V - NEGLIGENT MISREPRESENTATION

80. Plaintiff incorporates by reference all allegations in the preceding paragraphs as if fully set forth herein and further alleges as follows.

81. Defendants, and each of them, from the time that the Rejuvenate System was first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to Plaintiff and her surgeon, the medical, scientific, pharmaceutical and healthcare communities, and the public in general,

including, but not limited to, the misrepresentation that Rejuvenate Systems were safe, fit, and effective for implantation.

82. At all times relevant hereto, Defendant conducted a sales and marketing campaign to promote the sale of Rejuvenate Systems to surgeons conducting hip replacement surgeries during which Defendant, or its agents, misrepresented the health risks and consequences of the implantation of a Rejuvenate System.

83. These misrepresentations were made directly by Defendant, by sales representatives, detail persons and other authorized agents of Defendant, and in publications and other written materials directed to Plaintiff and her surgeon, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, with the intention of inducing reliance and the purchase and implantation of a Rejuvenate System

84. The foregoing representations by Defendants were, in fact, false, in that a Rejuvenate System is not, and at all relevant times alleged herein was not safe, fit, and effective for implantation, as a Rejuvenate System has a significant propensity to cause serious injuries to individuals, including, but not limited to, the injuries suffered as described above. The foregoing misrepresentations by Defendant were made with the intention of inducing reliance and inducing the purchase and implantation of a Rejuvenate System.

85. In reliance on the misrepresentations by Defendant, Plaintiff and her surgeon were induced to purchase and implant a Rejuvenate System. If they had known of the true facts and the facts concealed by Defendants, they would not have implanted a Rejuvenate System and their reliance upon Defendant's misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

86. As a direct and proximate result of Defendant's negligent misrepresentation of these material facts, Plaintiff suffered injuries and damages as described above.

87. Defendant's intentional disregard for the safety of patients who were implanted with Rejuvenate systems, including Plaintiff, justifies an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in her favor and seeks the following relief against Defendant:

a. Compensatory damages in excess of $75,000.00, exclusive of interest and costs;

b. Punitive damages;

c. Pre-judgment and post-judgment interest;

d. Costs and the expenses of this litigation;

e. Reasonable attorneys' fees and costs as provided by law; and

f. Such other relief as this Court deems just and proper under the circumstances.

DATED: March 18, 2013

RESPECTFULLY SUBMITTED,

THOMAS R. ANAPOL, ESQUIRE
Anapol Schwartz
1710 Spruce Street
Philadelphia, PA 19103
tanapol@anapolschwartz.com
T: (215) 735-1130
F: (215) 875-7707
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

DATED: March 18, 2013

THOMAS R. ANAPOL, ESQUIRE
Anapol Schwartz
1710 Spruce Street
Philadelphia, PA 19103
tanapol@anapolschwartz.com
T: (215) 735-1130
F: (215) 875-7707
Attorney for Plaintiff